rec'd 9/16/04

**American** 

15721 Bernardo Heights Parkway

Suite 151

San Diego, CA 92128 Office: 858-675-3600 Fax: 858-613-0748

Email: info@abgpharma.com http://www.abgpharma.com

September 7, 2004

Mr. Robert Moore Office of Nutritional Products HFS-811 **FDA** 5100 Paint Branch Parkway College Park MD 20740

Dear Mr. Moore,

We have been made aware of a regulation that requires our company to submit our labeling to you shortly after the initiation of commercial marketing. Please accept this submission for our product labeling as described in 21 CFR 101.93.

## 21 CFR 101.93 (2) (i)

Name and Address of Manufacturer:

Arizona Nutritional Supplements 380 East Chilton Drive Chandler, Arizona 85225

## 21 CFR 101.93 (2) (ii)

Text of the Statements:

The Hearing Pill contains pharmaceutical grade active ingredient and is measured to strictly conform with United States Pharmacopoeia. This product is protected under the US Navy and State University of New York #6,177,434 patent.

Mechanism: The Hearing Pill has demonstrated to help increase the levels of protective compounds and reduce the levels of destructive compounds in the cochlea.

Indications: The Hearing Pill is indicated for the remediation of the mechanisms that lead to permanent hearing loss, either before or shortly after noise trauma, after diagnosis by a qualified physician. Take only as part of an effective hearing conservation program.

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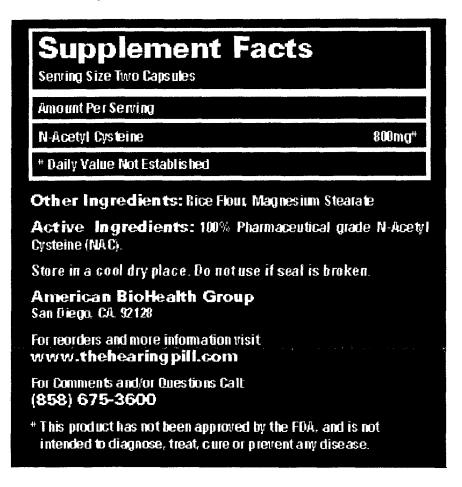
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Directions: Take two capsules twice daily before entering into a noisy environment such as a shooting range, rock concert or construction site. After experiencing nose trauma, see your physician immediately, and take two capsules three times daily for 30-60 days to attain the most positive effects.

Warnings: Seed the advice of a qualified health professional before using this product. The most common side effects are upset stomach and diarrhea. If symptoms continue to persist after a reasonable period of time, or if symptoms get worse, consult your doctor. Keep out of the reach of children.

The following "Supplement Facts" are on the left side of the product label:



I hereby certify that the information contained in this notice is complete and accurate, and that American BioHealth Group has substantiation that the statements are truthful and not misleading.

Best Regards,

Mark Mugerditchian President and COO

American BioHealth Group

Attachments: Full Product Label

Bonus Amount Included \* Bonus Amount Included \* Bonus Amount Included \* Bonus Amount Included

## Supplement Facts

Serving Size Two Capsules

Amount Per Serring

N-Acetyl Cysteine

890nig"

" Daily Value Not Established

Other Ingredients: Buce Hour Magnesium Stearate

Active Ingredients: 100% Pharmaceutical grade N-Acetyl Cysteme (NAC)

Store in a cool dry place. Do not use it seal is broken.

American BioHealth Group San Diego, CA 92128

For reorders and more information visit www.thehearingpill.com

For Comments and/or Questions Caft (8581 675-3600

" I his product has not been approved by the FBA, and is not intended to diagnose, treat, dure or prevent any disease.

## THE HEARING PILL Melps promote better hearing\*

Safety Tested and Quality Assured

90 EASY-TO-SWALLOW CAPSULES

Aids in Protecting Your Hearing\*

Guaranteed or your Money Back

PROTECTED UNDER U.S. PATENT 6,177,434

BioHealth

MADE DUTHE USA

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